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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,826	01/04/2001	Mohamed E. El Halawani	600.492US1	3468

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant(s)

09/754,826

Applicant(s)

EL HALAWANI ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18, 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/17/02 (Paper No. 17), is acknowledged.

Claims 1-3 and 5-28 are pending.

2. Claims 9-28 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

*Claims 1-3 and 5-8 are under consideration in the instant application.*

In view of the amendment, filed 12/17/02 (Paper No. 17), the following rejections remain

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

4. Claim 1-3 and 6-8 stand rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al.(US. Pat. No. 6,369,201, see entire document) for the same reasons set forth in the previous Office Action, Paper No: 13, mailed 06/06/02.

Applicant's arguments, filed 12/17/02 (Paper No. 17), have been fully considered, but have not been found convincing.

Applicant asserts that : (i)Barker et al. do not teach or suggest claimed immunoconjugate, because the body weights for the group treated with a recombinant myostatin immunoconjugate were not significantly different from the body weights in control groups i.e. the reconstituted myostatin immunoconjugate did not elicit an immune response; (ii) Barker et al., only describes ten myostatin oligonucleotides to be employed in a reconstructed myostatin sequences .

Contrary to Applicant's assertion Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier . ( see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). In Detailed Description, Barker et al. teach that the term "myostatin immunogen" includes polypeptide of myostatin

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molecule, which elicits an immunological response (see column 6, lines 14-25, column 15 lines 1-5, and column 16, lines 42-45). Moreover, Applicant himself acknowledges that, Barker et al. disclosed a myostatin immunoconjugates capable of eliciting an immune response in a vertebrate subject (see page 3 of Applicant's arguments, filed 12/17/02, Paper No. 17 in particular). Barker et al. also teach vaccine composition comprising the myostatin polypeptide and pharmaceutically acceptable excipient (Column 4, line 10-15). In Detailed Description, Barker et al. teach that myostatin molecule is administered in the mix with a pharmaceutically acceptable excipient, such as water, saline, dextrose, glycerol, ethanol. (Column 23, lines 45-65).

Barker et al. also teach that to enhance immunogenicity of myostatin, myostatin immunoconjugate which comprises a fusion polypeptide can be used. (see Detailed Description, Column 10, lines 5-10).

With regards to Applicant's arguments that Barker et al., only describes ten myostatin oligonucleotides to be employed.

Contrary to Applicant's assertion, Barker et al. also teach myostatin peptides consisting about 3 to about 200 amino acids, or consisting a mature form of myostatin spanning from amino acid 1 through 350 that are derived from various vertebrate species, including turkey myostatin (see column 3, lines 25-45 and Fig. 1A-1D). In column 4, line 55, Barker et al. teach turkey myostatin (SEQ ID No: 35) that comprises SEQ ID NO: 2 of the instant claim 3.

The reference teaching anticipates the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3 and 5-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. (US. Pat. No. 6,369,201) in view of Harris et al. (Micron 1999, 30, 597-623) for the same reasons set forth in the previous Office Action, Paper No: 13, mailed 06/06/02.

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Applicant's arguments, filed 12/17/02 (Paper No. 17), have been fully considered, but have not been found convincing.

Applicant asserts neither Barker et al. nor Harris et al. disclosed or suggest a myostatin immunoconjugate, comprising the mature form of vertebrate myostatin linked to the carrier.

Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see *In re Keller*, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. *In re Young* 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

Contrary to Applicant's assertion, as was discussed above, it is the Examiner position that Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier. ( see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). Barker et al. further teach that immunological carrier can be any molecule which, when associated with a myostatin immunogen, enhances the immunogenicity of the molecule. (Column 9, lines 22-34). Barker et al. do not explicitly teach that the carrier is KLH.

However, Harris et al. teach the widespread use of KLH as a hapten carrier and generalized vaccine component that is widely used to enhance the immunogenicity of the vaccine ( see Abstract and entire document).

Given the teaching of Harris et al. that KLH is widely used as a carrier to enhance the immunogenicity of the vaccine, one of ordinary skill in the art would have found it obvious to modify the teaching of Barker et al. and substitute carrier described by Barker et al. for KLH carrier to enhance the immunogenicity of myostatin immunoconjugate. One of ordinary skill in the art at the time the invention was made would be motivated to substitute immunological carrier, described by Barker et al. for KLH carrier to enhance the immunogenicity of myostatin immunoconjugate. Finally, given the art recognizes widespread use of KLH as a carrier to enhance the immunogenicity, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to generate a myostatin immunoconjugate, comprising a myostatin polypeptide linked to KLH as a carrier.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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September 22, 2003

  
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